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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,262	11/18/2005	Breda Mary Cullen	JJM0618USPCT	9333
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PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			KLINKEL, KORTNEY L	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/528,262	Applicant(s) CULLEN ET AL.	
	Examiner KORTNEY KLINKEL	Art Unit 4131	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims

Receipt is acknowledged of a preliminary amendment filed on March 17, 2005 in which claims 3-6, 8-10, and 19 were amended and claims 14-18 and 20 were canceled. Claims 1-13 and 19 are pending in the instant Office action.

IDS

Acknowledgement is made of applicant's submitting of the information disclosure statement (IDS) on March 17, 2005. Applicant lists US-2157224 on the IDS and refers to it in the specification (page 12, lines 21-23) as pertaining to a collagen-based sponge. However, US patent number 2157224 pertains to a method for producing motor fuels. Appropriate corrective action is respectfully requested.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in

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scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Applicant is advised that should claim 1 be found allowable, claim 12 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). It is the examiner's position that a wound dressing composition is equivalent to a wound dressing.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 5-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cullen et al. WO 00/33893.

Applicants are claiming a wound dressing composition comprising (i) chitosan and (ii) oxidized cellulose.

Cullen teaches a sterile composition which can be used as a wound dressing (claim 19 and page 9, lines 6-10) comprising a polysaccharide selected from the group including oxidized celluloses and chitosans, and salts and mixtures thereof (claim 8). Cullen further teaches that oxidized regenerated cellulose (ORC) is especially preferred (page 6, lines 13-14). Cullen does not specifically exemplify a composition comprising both oxidized cellulose and chitosan. However, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time of the instant invention to obtain a wound dressing composition comprising (i) chitosan and (ii) oxidized cellulose, more specifically ORC, because Cullen teaches a sterile composition which can be used as a wound dressing (claim 19) including a therapeutic peptide and a polysaccharide selected from the group consisting of oxidized celluloses, chitosans and salts and mixtures thereof (claims 1 and 8). Therefore, it has been shown that not only does a composition consisting of oxidized cellulose function as a wound dressing, but also a composition consisting of chitosan. Cullen also states that mixtures of the two polysaccharides are suitable for use. Thus, combining two things that are each respectively recognized as being suitable in the prior art for a given purpose, one would have a reasonable expectation of success upon their combination. See *In re Kerkhoven*, 626 F.2d 846, 850 and also *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992) 205 USPQ 1069, 1072 (CCPA 1980). Thus, instant claims 1, 2 and 5 are *prima facie* obvious over the teaching of the prior art.

Instant claim 9 states the wound dressing composition is a flexible film. In light of that addressed above and in addition to the fact that Cullen teaches a sterile composition in the form of a polymer film (claim 19), instant claim 9 is *prima facie* obvious over the teachings of the prior art due to the fact that a polymer film can be

flexible. Due to the fact that the recited components of the claimed composition are substantially similar to those taught by Cullen in the prior art, there is a reasonable expectation that a film of the composition suggested by the prior art would also be flexible.

Instant claim 13 calls for the wound dressing to be sterile and packaged in a microorganism-impermeable container. In addition to that stated above, Cullen further teaches a composition which is to be sterile packaged. Instant claim 13 is *prima facie* obvious over the teachings of the prior art due to the fact that it would be obvious to one of ordinary skill in the art that a microorganism-impermeable container would necessarily be sterile by definition. It would also have been common sense to place a wound dressing in a microorganism impermeable container, because it is bad medical practice to put a microorganism permeated wound dressing (i.e. non-sterile) on a wound. Thus, it would make no sense to place a wound-dressing in a container that were permeable to microorganism, as this would defeat the purpose of the wound dressing.

Moreover, as stated above, Cullen teaches that mixtures of polysaccharides, namely oxidized cellulose and chitosan are functional as wound dressings. This teaching is implicit of all conceivable ratios. Instant claims 10 and 11 state a range of oxidized cellulose to chitosan ratios respectively. It would have been in the capacity to one of ordinary skill in the art to mix the two polysaccharides in the stated ratios in instant claims 10 and 11, based on the fact that both oxidized cellulose and chitosan have been shown to have the same function in this context. This is an optimization of ranges and as such is considered to be *prima facie* obvious when the general conditions of a claim, i.e. combining chitosan and oxidized cellulose for wound dressings, are disclosed in the prior art (see *In re Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382, see also MPEP 2144.05).

Instant claims 6 and 7 call for a wound dressing composition wherein the polysaccharides (in the instant case, oxidized cellulose and chitosan) make up at least 25% and 50% respectively by weight of the material on a dry weight basis. In addition to that shown above, Cullen also teaches two compositions containing 45% by weight of

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ORC (example 2) and 45% by weight chitosan (example 5) respectively. Furthermore, Cullen teaches a composition containing 80% by weight of ORC fibers (example 2). The 45% by weight is an exemplified embodiment and by no means an upper limit since the composition is explicitly contemplated to comprise at least 80% polysaccharide. Additionally, 45% by weight is for all intents and purposes the same as 50%, see *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Therefore, instant claims 6 and 7 are *prima facie* obvious over the teachings of the prior art because not only has Cullen shown that both ORC (an oxidized cellulose) and chitosan but also mixtures thereof function as wound dressing compositions so it would be obvious to one skilled in the art to mix ORC and chitosan in a wound dressing composition in an amount greater than 50% by weight.

Instant claim 8 calls for a wound dressing composition further comprising from about 0.01 to about 5% by weight on a dry weight basis (relative to the polysaccharides of claim 1) of one or more wound healing therapeutic substances. In addition to that shown above, Cullen further teaches a composition wherein the weight ratio of said therapeutic peptide to said polysaccharide is from 1:10⁶ to 1:10 (claim 11). Examiner is interpreting the therapeutic peptide to read on a wound healing therapeutic substance. Thus, instant claim 8 is *prima facie* obvious over the teachings of the prior art because it would be obvious to one skilled in the art that a therapeutic peptide is a wound healing therapeutic substance. Furthermore, it would be obvious to one of ordinary skill in the art that the range by dry weight of about 0.01 to about 5% clearly falls into the range of therapeutic peptide to polysaccharide from 1:10⁶ to 1:10. Thus, optimization of the range of therapeutic peptide would yield the amount required by Applicants for the claimed wound healing therapeutic substance.

In conclusion, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time of the instant invention to obtain a wound dressing composition comprising (i) chitosan and (ii) oxidized cellulose, more specifically ORC because Cullen teaches a sterile composition which can be used as a wound dressing (claim 19) including a therapeutic peptide and a polysaccharide selected from the group consisting of oxidized celluloses, chitosans and salts and mixtures thereof (claims 1 and 8). Cullen

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demonstrates that not only does a composition consisting of oxidized cellulose function as a wound dressing, but also a composition consisting of chitosan. Cullen also states that mixtures of the two polysaccharides are suitable for use (claim 8). Thus, combining two things that are each respectively recognized as being suitable in the prior art for a given purpose, one would have a reasonable expectation of success upon their combination. Examiner acknowledges Applicants' data in Figures 1-2 and has determined that this data is insufficient to overcome the instant rejection because the data contained in Figures 1-2 depict elastase and collagenase activity, respectively, versus time for a negative control (gauze), a positive control (collagen/ORC sponge) and instant claimed invention, ORC/chitosan and Applicants' claimed invention performs within error identical to the collagen/ORC sponge. In the absence of evidence showing that collagen and not ORC is the active ingredient in the collagen/ORC sponge, Applicants' data further supports Examiner's arguments stated above. Namely that both oxidized cellulose and chitosan separately have been shown to be suitable for use in wound dressings, one of ordinary skill in the art would have a reasonable expectation of success upon their combination—as is shown in Applicants' Figures 1 and 2. In addition, Applicants' data in Figures 1-2 are not commensurate in scope with what is being claimed, because Applicants' data is limited to compositions comprising ORC/chitosan, whereas the majority of Applicants' claims do not require ORC. Therefore, instant claims 1, 2, 5-13 are *prima facie* obvious over the teaching of Cullen et al. WO 00/33893.

Claims 1, 3, 4, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watt et al. WO 98/00180 and in further view of Cullen et al. WO 00/33893

In instant claim 3, applicants are claiming a wound dressing composition comprising (i) chitosan and (ii) an oxidized cellulose wherein said oxidized cellulose is in the form of dispersed fibers or powder. In instant claim 4, applicant is claiming that the polysaccharides are to be dispersed in a semi-solid or solid vehicle for topical application

Watt teaches the use of oxidized cellulose, preferably ORC, and complexes thereof (abstract) for the preparation of a medicament for the treatment of a chronic wound wherein the oxidized cellulose is in the form of dispersed fibers or powders (claims 1 and 3). Watt further teaches the dispersion of said fibers or powder in a semi-solid vehicle for topical application (claim 4). Watt fails to exemplify a wound dressing comprising both oxidized cellulose and chitosan. However, Cullen, as outlined above, teaches that combinations of polysaccharides can function as wound dressings. Instant claims 3 and 4 are *prima facie* obvious over the teachings of the combined prior art because it would be obvious to one of ordinary skill in the art to disperse the oxidized cellulose in the form of dispersed fibers or powders and also to disperse the polysaccharides in a semi-solid or solid vehicle for topical application since the polysaccharides of interest have a common function.

In instant claim 19, applicants claim a method of preparing an active wound dressing material comprising the steps of: (i) contacting said composition with a biological medium containing cell growth factors to bind the cell growth factors to the material and (ii) washing and drying the material having the cell growth factors bound thereto to form said active wound dressing material.

In light of the above arguments and in addition to the fact that Watt teaches a method of preparing an active wound dressing material comprising the steps of: (i) contacting a material comprising oxidized cellulose or a complex of oxidized cellulose with a structural protein with a biological medium containing cell growth factors to bind the cell growth factors to the material and (ii) washing and drying the material having the cell growth factors bound thereto to form said active wound dressing material (claim 21). Instant claim 19 is *prima facie* obvious over the teachings of the prior art because it would be obvious to an artisan of ordinary skill to follow the above steps of (i) washing... and (ii) drying... regardless of the combination of polysaccharides used in the composition of the wound dressing.

In conclusion, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time of the instant invention to obtain a wound dressing composition as enumerated in instant claims 1, 3 and 4 because Watt teaches the use of oxidized

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cellulose, preferably ORC, and complexes thereof (abstract) for the preparation of a medicament for the treatment of a chronic wound wherein the oxidized cellulose is in the form of dispersed fibers or powders (claims 1 and 3). Watt further teaches the dispersion of the said fibers or powder in a semi-solid vehicle for topical application (claim 4). Whereas Watt fails to exemplify a wound dressing comprising both oxidized cellulose and chitosan, Cullen, clearly teaches this combination as outlined above. One of ordinary skill in the art would expect a reasonable degree of success in combining the teachings of Watt and Cullen because both oxidized cellulose and chitosan have been shown to be functional equivalents (Cullen). Therefore dispersing them in a manner taught by Watt would have been obvious to one of ordinary skill in the art. By the same token, the method in instant claim 19 would have been *prima facie* obvious to a person of ordinary skill in the art at the time of the instant invention in light of the teachings of Cullen. Examiner acknowledges Applicants' data in Figures 1-2 and has determined that this data is incommensurate in the scope of said claims. In conclusion, instant claims 1, 3-4 and 19 are *prima facie* obvious over the teaching of Watt and in further view of Cullen et al. WO 00/33893.

Conclusion

Claims 1-13 and 19 are rejected. Currently no claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KORTNEY KLINKEL whose telephone number is (571)270-5239. The examiner can normally be reached on Monday-Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres (571)272-0867 or Cecilia Tsang (571)272-0562 can be reached at the respective numbers. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KLK

/Cecilia Tsang/
Supervisory Patent Examiner, Art Unit 4131